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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/831,907 | 09/18/2001 | Jean-Claude Beauvillain | 208888USOPCT | 3062 |

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/831,907

Applicant(s)

BEAUVILLAIN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 9, 10, 14 and 15, drawn to a polypeptide comprising at its C-terminus the heptapeptide Cys-Phe-Trp-Lys-Tyr-Cys-Xaa, wherein Xaa represents Val or Ile, and having at least 45% similarity with the polypeptide sequence set forth as SEQ ID NO:1, pharmaceutical compositions comprising the polypeptide and methods of using the polypeptide.

Group II, claim(s) 3-9 and 13, drawn to a purified nucleic acid fragment wherein said nucleic acid fragment constitutes at least an oligonucleotide derived from a fragment consisting of a sequence encoding a polypeptide of Group I or complement thereof, a vector, host cell and kit comprising said purified nucleic acid fragment, wherein said fragment a human sequence.

Group III, claim(s) 3-9 and 13, drawn to a purified nucleic acid fragment wherein said nucleic acid fragment constitutes at least an oligonucleotide derived from a fragment consisting of a sequence encoding a polypeptide of Group I or complement thereof, a vector, host cell and kit comprising said purified nucleic acid, wherein said fragment a mouse sequence.

Group IV, claim(s) 3-9 and 13, drawn to drawn to a purified nucleic acid fragment wherein said nucleic acid fragment constitutes at least an oligonucleotide derived from a fragment consisting of a sequence encoding a polypeptide of Group I or complement thereof, a vector, host cell and kit comprising said purified nucleic acid, wherein said fragment a rat sequence.

Group V, claim(s) 10, drawn to a method of using the nucleic acids of Group II for preparing a medicinal product to treat neurodegenerative diseases.

Group VI, claim(s) 10, drawn to a method of using the nucleic acids of Group III for preparing a medicinal product to treat neurodegenerative diseases.

Group VII, claim(s) 10, drawn to a method of using the nucleic acids of Group IV for preparing a medicinal product to treat neurodegenerative diseases.

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Group VIII, claim(s) 11 and 12, drawn to a process for detecting the presence of absence of an mRNA or a mutation in a nucleic acid according to Group II.

Group IX, claim(s) 11 and 12, drawn to a process for detecting the presence of absence of an mRNA or a mutation in a nucleic acid according to Group III.

Group X, claim(s) 11 and 12, drawn to a process for detecting the presence of absence of an mRNA or a mutation in a nucleic acid according to Group IV.

The inventions listed as Groups I and II-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. All the groupings are directed to products or methods of using molecules related to Urotensin II but Group I has a special technical feature not shared by Groups II-X. Group I is directed to polypeptides which have the special technical feature of a defined amino acid sequence while Groups II-X are directed to nucleic acid molecules which are not limited to molecules encoding the polypeptides of Group I, as the claims also encompass "derivatives" or fragments of nucleic acids encoding Urotensin II.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups II-X do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group II is a sequence encoding the human urotensin II polypeptide, which is shown by EMBL AF172174, cited on the International Preliminary Examination Report, to lack novelty or inventive step. As the product claims do not represent a contribution over the prior art, the claims lack a special technical feature that is the same as or corresponds to a special technical feature of the other claimed inventions. Thus, there is no special technical feature linking the recited groups as would be necessary to fulfill the requirement for unity of invention.

The products of Groups II, III and IV are distinct in being directed to polynucleotides encoding structurally unique polypeptides, and fragments and derivatives thereof. Each Group therefore encompasses a structurally and functionally distinct nucleic acid molecule, which not disclosed as capable of use together with the molecules of the other Groups.

The methods of Groups V, VI and VII are distinct in being directed to methods of preparing medicinal products comprising each of the distinct polynucleotides of Groups II, III and IV, respectively.

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The methods of Groups VIII, IX and X are directed to processes of detecting the presence or absence of an mRNA or nucleic acid according to each of the distinct polynucleotides of Groups II, III and IV, respectively.

The methods of Groups V, VI and VII are distinct from the methods of Groups VIII, IX and X because the methods are not disclosed as capable of use together in a single process and have different modes of operation, functions and effects as Groups V, VI and VII are directed to a method of manufacture while Groups VIII, IX and X are directed to a method of detection or diagnosis.

The products of Groups II, III and IV are distinct from the methods of V, VI and VII, respectively, because the products as claimed can be used in materially different methods such as nucleic acid hybridization assays.

The products of Groups II, III and IV are distinct from the methods of VIII, IX and X, respectively, because the products as claimed can be used in materially different methods such as in the production of medicinal products according to the inventions of Groups V, VI and VII.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on 703-305-1998. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
November 29, 2002



JAMES KETTER
PRIMARY EXAMINER